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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/691,014 | 10/21/2003 | Scott E. Boatman | 8627-325 | 9347 |

7590

10/19/2004

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| EXAMINER |
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JACKSON, SUZETTE JAMIE

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| ART UNIT | PAPER NUMBER |
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3738

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/691,014

Applicant(s)

BOATMAN, SCOTT E.

Examiner

Suzette J Jackson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. Applicant's amendment dated 7/12/04 has been received in application serial number 10/691,014.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-5, 7, 10-11, 14, 17, 19 and 21-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham et al. 2003/0171824 in view of Narcisco, Jr. 5,429,634. Abraham et al. discloses the invention as claimed comprising : A cannula [0017] formed from at least a first layer and a second layer [0018...*two or more layers...*], wherein the first layer and second layer each are made of different non-synthetic [0011....*or from different collagen materials...*], natural tissue without the presence of a synthetic support structure; wherein the cannula comprises an opening extending through a wall defined by the first layer and second layer; made of small intestine submucosa [0014-0016]; including growth factors [0018 pg. 3 growth factors]. However Abraham et al. does not illustrate struts. Narcisco Jr. teaches a tissue-

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engineered stent with a strut pattern configuration (see figures 45 and col.2, lines 47-48). It would have been obvious as the time the invention was made to take the tissue device of Abraham et al. and make it to have defined struts as shown by Narciso Jr. because Abraham et al. states in section [0012] that physical modification such as shaping...and perforating can be made to the device and by using a uniform perforated pattern the left over material would equate to "struts".

Claims 2, 6, 8-9, 12, 15, 20 and 28 rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham et al. in view of Narciso Jr. and further in view of Schaldach et al. Abraham et al. and Narciso Jr. have been disclosed however they do not teach the use of cartilage. Schaldach et al. teaches a tubular conduit for vascular use manufactured from cartilage (see [0012; 0018; 0021; 0042; 0053; 0060; 0068]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the inventions of Abraham and Narciso Jr. and incorporate a layer of cartilage (by any alternating layer design) because Abraham discloses in section [0011] that two or more different types of material having collagen may be utilized for the layers and that they may be bonded together and Abraham also discloses that the material may be layered with other materials to form as stent [0019].

4. Claims 13 and 16 are under 35 U.S.C. 103(a) as being unpatentable over Abraham et al. in view of Narciso Jr. and further in view of Yang 6,613,082. Abraham

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et al. and Narcisco Jr. have been disclosed above however they do not specify the use of Paclitaxel. Yang teaches a stent graft with a protein matrix that utilizes Paclitaxel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize Paclitaxel in the invention of Abraham et al. because it is well known that Paclitaxel is used to treat the implanted area of a vessel.

5. Claims 9, 13, 18, 30 and 31-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham in view of Narciso Jr. and further in view of Sabolinski 2004/0002772. Abraham et al. and Narciso Jr. have been disclosed however they do not specify laser cutting of openings into the structure. Sabolinski teaches a tubular bi or tri-layered implant made from small intestine material [0011] that have perforations formed utilizing a laser [0024]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the inventions of Abraham et al. and Narciso Jr. and make the perforations/openings by using a laser in order to let surrounding tissue to become incorporated with the device in order to secure it into the vessel or organ.

Response to Arguments

6. Applicant's arguments with respect to the claims have been considered but are moot in view of this new ground(s) of rejection. Applicant contends that no struts are

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formed by the perforations of Abraham et al. Narsico Jr. teaches that it has been known that tissue engineered stents have been formed with strut patterns.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 703-308-65168.

8. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

A handwritten signature in cursive script, appearing to read 'Suzette J. Jackson', followed by a long horizontal flourish.

Suzette J. Jackson
15 October 2004